Section 8 - 510(k) Summary

JUL 1 2 2013

Date:	14 May 2013
Sponsor:	Nexxt Spine 14425 Bergen Blvd, Suite B Noblesville, IN 46060 Mobile: 317-224-4223 Office: 317-436-7801 Fax: 317 245-2518
Contact Person:	Eric Lintula, Director of Engineering
Trade Names:	Facet Fixx™
Device Classification	Unclassified
Common Name:	Facet screw spinal device
Regulation:	N/A (unclassified)
Device Product Code:	MRW
Device Description:	The Facet Fixx™ System is a posterior facet spinal fixation system consisting of screws with and without washers. The cannulated screw is offered partially or fully threaded in various diameter and length combinations.
Intended Use:	The Facet Fixx™ System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. For transfacet fixation, the screws are inserted through the inferior articular process across the facet joint and into the pedicle. For translaminar facet fixation, the screws are inserted through the lateral aspect of the spinous process, through the lamina, through the inferior articular process, across the facet joint and into the pedicle. The Facet Fixx System is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels from C2 to S1 inclusive. The Facet Fixx System is indicated for treatment of any or all of the following: Degenerative disc disease (DDD) as defined by back pain of discogenic origins confirmed by history and radiographic studies, Degenerative disease of the facets with instability, Trauma (i.e. fracture or dislocation), Spondylolisthesis, Spondylolysis, Pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity.
Materials:	The Facet Fixx™ System is manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.
Predicate Devices:	Discovery® Facet Screw (K012773), CHAMELEON™ (K071420) and the TOWNLEY (K953076/K003928/K021705)
Performance Data:	Static and dynamic cantilever bending (ASTM F2193) and axial pullout tests (ASTM F543) were used to characterize the mechanical properties of the Facet Fixx™ System. The mechanical test results demonstrate the Facet Fixx™ System to be substantially equivalent to the predicate devices.

Technological Characteristics:

The Facet Fixx™ System possesses the same technological characteristics as the predicates. These include:

- basic design (full and partial threaded screw fixation system),
- material (titanium alloy),
- sizing: sizes (diameter and lengths) are within the range of those offered in the predicate systems, and
- anatomic location.

Therefore the fundamental scientific technology of the Facet Fixx™ System is the same as previously cleared devices.

Conclusion:

In comparison to the predicate devices, the Facet Fixx™ System has

- the same intended use (as described above),
- the same technological characteristics or different without raising safety and effectiveness issues (as described above)

Therefore the Facet Fixx™ System can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 12, 2013

Nexxt Spine, LLC
% BackRoads Consulting, Incorporated
Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026-2141

Re: K131417
Trade/Device Name: Facet Fixx™ Spinal Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: May 14, 2013
Received: May 16, 2013

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that,FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 - Indications for Use Statement

510(k) Number: K131417

Device Name: **Facet Fixx™ Spinal Fixation System**

Indications for Use:

The Facet Fixx System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. For transfacet fixation, the screws are inserted through the inferior articular process across the facet joint and into the pedicle. For translaminar facet fixation, the screws are inserted through the lateral aspect of the spinous process, through the lamina, through the inferior articular process, across the facet joint and into the pedicle.

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- Degenerative disease of the facets with instability
- Trauma (i.e. fracture or dislocation)
- Spondylolisthesis
- Spondylolysis
- Pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131417